

## **REMARKS/ARGUMENTS**

### **In the Claims**

Claims 1-31 remain in this application.

### **§ 102 and 103 Rejections**

The Examiner has rejected claims 1-13, 16-25, 30-31 under 35 U.S.C. 102(b) as being anticipated by McKenzie et al (US 5,993,469), claims 1-13, 16-25, 28-31 are rejected under 35U.S.C 103(a) as being unpatentable over McKenzie et al in view of Milo et al (US 5,429,136) and claims 1, 14, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie et al in view of Masch (US 4,728,319). The Examiner's rejections are respectfully traversed.

In citing McKenzie et al., the Examiner states,

“...McKenzie et al disclose a method and apparatus for reducing restriction of blood flow in a lumen of a blood vessel comprising inserting imaging guidewire into the lumen capable of generating cross-sectional images of the lumen (Col 9 Line 35-50, Col 11 Line 65-Col 12 Line 65, Col 18 Line 30-45), propelling a catheter including a "working head" over the imaging system to the plaque (Col 11 Line 16-65), scanning the lumen with the imaging system to image the lumen (Col 11 Line 65-Col 12 Line 65), positioning the catheter in the lumen using a position element and monitoring the image to determine of the head is positioned in a desired location (Col 18 Line 5-45), and finally operating the working head to remove the intraluminal plaque (Col 19 Line 10-Col 20 Line 5)...” (emphasis added)

Applicant has reviewed the McKenzie et al. document and especially those passages cited by the Examiner. Applicant respectfully points out that while McKenzie et al. makes numerous references to an imaging catheter, the term “guidewire” is used only three times in the entire document; in column 3, line 58 in reference to a prior art document; in column 7, line 2 where it is used in the phrase “conventional guidewire”, and in column 19, lines 44-45 where it is again used in the

phrase "conventional guidewire." Therefore, Applicant asserts that McKenzie et al. does not teach the use of an imaging guidewire.

Regarding the Examiner's assertion that McKenzie et al. teaches propelling a catheter including a "working head" over the imaging system to the plaque in column 11, lines 16-65, Applicant fails to find such teaching neither in the referenced passage nor elsewhere in McKenzie et al. Applicant contends that in column 11, lines 16-65, McKenzie et al. clearly teaches the use of a steerable catheter configured with pull wire steering components. That is, pull wires that at one end are connected to the tip of the catheter and at the other end accessible to the user such that pulling the pull wires changes the orientation of the catheter tip so as to "steer" the catheter as it is advanced in the lumen. This is particularly clear in column 11, lines 39-44 which state,

"...In particular, it is desirable to have a catheter having steering capabilities so that the tip can be guided to position the atherectomy assembly to engage plaque. Steerability can be accomplished using pull wires in accordance with techniques known in the art..." (emphasis added)

Applicant would also like to respectfully point out that with regard to Figure 2 (column 9, lines 38-50) where McKenzie et al. describes the only embodiment of a catheter that includes an imaging device, McKenzie et al. clearly teaches that the imaging device is configured in the working head.

Applicant asserts that there is no reference in the passage found in column 11, lines 16-65 to propelling the catheter over an imaging guidewire and that McKenzie clearly teaches a working head that when propelled carries the imaging device with it.

This is in clear contrast to the teachings of the present invention and especially as claimed in claim 1, which recites:

“(a) inserting an imaging guidewire into the lumen of the blood vessel to the intraluminal plaque, said imaging guidewire capable of generating a cross-sectional image of the lumen;  
(b) propelling a catheter including a working head over said imaging guidewire towards said intraluminal plaque until said catheter reaches a distal end of said guidewire;” (emphasis added)

and claim 16, which recites:

“a) an imaging guidewire insertable in the lumen of the blood vessel, said imaging guidewire capable of generating digital data which describe a cross-sectional image of the lumen and communicating said digital data to a central processing unit (CPU) and further capable of guiding a catheter to the intraluminal plaque without traversing the plaque;” (emphasis added)

Therefore, Applicant respectfully asserts that McKenzie et al. clearly does not disclose either the method or the apparatus of the present invention and therefore, independent claims 1 and 16 in condition for allowance.

Applicant further asserts that since both Milo et al. and Masch are each cited separately as basis for rejecting claims that are depended from base claims that have now been shown to be allowable, such rejection are now moot.

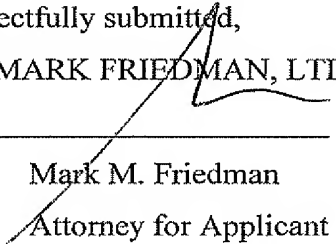
Applicant would, however, like to respectfully point out that although the Examiner cited Milo et al. as teaching “...in the same area of endeavor the use of an Archimedes screw device for plaque removal (Fig 5, 8 and Col 15 Line 50 - Col 16 Line 58)...”, Applicant learns Milo differently. Applicant has reviewed the referenced passage of column 15, line 50- column 16, line 58, and did not find the term “Archimedes screw” nor any wording describing the function of an Archimedes screw. In review Figures 5 and 8 as referenced by the Examiner, applicant notes that elements “90” in Figure 5 and “122” in Figure 8 that resemble an Archimedes screw are, in fact, described in the specification as “wire connectors”. Regarding Figure 5,

column 11, lines 11-15 describe wire connectors 90 that Applicant suggests are illustrated coiled around the torque tube 88. Regarding Figure 8, Applicant suggests the wire connectors 122 (column 12, line 51) are illustrated coiled around the cutter torque cable 110.

The Applicant believes that the above comments completely overcome the Examiner's rejections of claims 1 and 16 on §102(b) and §103(a) grounds, and therefore the rejections of claims 2-15 and 17-31, which depend therefrom, are now rendered moot.

In view of the above remarks, it is respectfully submitted that the claims are in condition for allowance.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,  
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